

REMARKS

In the specification, applicants have amended the section titles to comport, as near as possible, to the guidelines outlined in 37 C.F.R. § 1.77(b). Additionally, applicants have included a "Brief Description of the Drawings" section between the "Summary of the Invention" and the "Detailed Description of the Invention." Support for this subject matter is found on pages 23 and 24 of the specification as originally filed.

Claims 1-10 are currently pending in this application.

Applicants have canceled claims 11-22 in accordance with Applicants' election of claims 1-10 in response to the June 27, 2005 Restriction Requirement. This cancellation is made without prejudice and without waiver of applicants' right to pursue these claims in a continuation or divisional application claiming priority herefrom under 35 U.S.C. § 120.

In order to clarify the scope of the claims, applicants have amended claim 1. For example, applicants have amended claim 1 to recite that the inner surfaces of the inhaler contain elevations and/or depressions with a height/depth of from 0.1 to 100 microns "so that the inner surface(s) of the inhaler may be kept clean without affecting the delivery characteristics of the composition." Support for this amendment is found in the specification, e.g., on page 5, line 11, to page 6, line 14.

No new matter is being presented by this amendment.

A. Rejections under 35 U.S.C. § 103

Claims 1-7, 9 and 10 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hochrainer et al. (U.S. Patent 5,947,118, hereinafter "Hochrainer") in view of Datta et al. (U.S. Patent 5,871,010, hereinafter "Datta"). Additionally, claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Hochrainer and Datta in view of Kladders (U.S. Patent 4,889,114, hereinafter "Kladders"). Applicants respectfully traverse these rejections.

The grant of a patent is precluded "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time of the invention was made to a person of ordinary skill in the art." 35 U.S.C. § 103(a). Furthermore, the standard for obviousness is set out in *Graham v. John Deere Co.* and is based on several underlying factual inquiries, including (1) determining the scope and content of the prior art, (2) resolving the level of skill of a person

of ordinary skill in the art, (3) ascertaining the differences between the claimed invention and the teachings of the prior art, and (4) evaluating any objective indicia of non-obviousness, e.g., long-felt need, commercial success, failure of others, copying, unexpected results or other secondary considerations (383 U.S. 17-18, 86 S.Ct. 684).

In considering and determining patentability under 35 U.S.C. § 103, Patent Examiners are responsible for applying the *Graham* factors in each and in every case (MPEP 2141(I)). Moreover, the Examiner bears the initial burden of factually supporting a *prima facie* conclusion of obviousness, which is established by meeting three basic criteria – (1) suggestion or motivation to modify the reference or to combine reference teachings, (2) reasonable expectation of success and (3) prior art reference (or references when combined) must teach or suggest all the claim limitations (MPEP 2142). As discussed below, the Examiner's combinations of a primary reference(s) with a secondary reference does not meet the requirements necessary to establish a *prima facie* case of obviousness.

As amended, claim 1 of the present invention is directed to an inhaler comprising a mouthpiece and an air channel opening into the mouthpiece and optionally a chamber, wherein at least part of the inner surface(s) of the mouthpiece and/or air channel and/or chamber contains elevations and/or depressions with a height/depth of from 0.1 to 100 μm so that the inner surface(s) of the inhaler may be kept clean without affecting the delivery characteristics of the composition. Claims 2-10 depend either directly or indirectly from claim 1. As such, applicants' claimed invention relates to a powder inhaler that can be cleaned more efficiently without affecting the delivery characteristics of the powder formulation (see page 6 of specification, lines 7-9). In essence, the claimed invention is directed to a hygienically improved powder inhaler.

According to the Examiner, Hochrainer discloses a mouthpiece, an air channel opening into the mouthpiece and a chamber but lacks inner surface elevations and/or depressions as taught by the present invention. The Examiner also asserts that Datta discloses an inhaler apparatus with a modified surface for enhanced release of dry powders and that the surface of the substrate and the mouthpiece have elevations and depressions with a depth of one micron to about 2.5 microns. The Examiner then argues it would have been obvious to one of skill in the art to modify the device of Hochrainer with the depressions taught by Datta in order to decrease the area of contact between the selected medicaments, thus obviating the subject matter of claims 1-7 and 9-10.

Applicants note that Hochrainer is directed to an inhaler that allows for ease of fixing and removing capsules from the inhaler (col. 1, lines 35-39), whereas Datta is directed to surface modifications to minimize the area of contact between the medicament and the surfaces of the inhaler to allow accurate delivery of the medicament at a low flow rate (col. 1, lines 35-38; col. 2, lines 8-12). In contrast, applicants' claimed invention is directed to an inhaler having inner surface modifications that are particularly suitable for washing and re-use without diminishing delivery characteristics of additionally-loaded pharmaceuticals. As such, there is no nexus between the claimed subject matter of the present invention and the teachings of Hochrainer and Datta.

Moreover, the three basic criteria for a *prima facie* case of obviousness are not satisfied. For example, there is no suggestion or motivation to modify or combine reference teachings to arrive at the presently claimed subject matter because the problems to be solved in the present application (cleaning/hygiene) and the reference teachings (ease of fixing/removing capsules; and decreasing area of contact between selected medicament and surface) are different. Second, there is no reasonable expectation of success because one of skill in the art would not necessarily expect elevations and depressions in a surface to "facilitate cleaning," as one may expect with a smooth surface construction. Finally, the combination of the prior art references do not teach or suggest all of the claim limitations of the present claims. For these reasons, applicants respectfully request that the Examiner withdrawal the § 103(a) rejections of claims 1-7 and 9-10.

The Examiner has also rejected claim 8 as being unpatentable over Hochrainer and Datta in view of Kladders. As discussed above, Hochrainer and Datta do not meet the criteria necessary to establish a *prima facie* case of obviousness. The additional Kladders reference does not cure this defect, as it relates to capsule chamber diameter. For this reason, applicants respectfully request that the Examiner withdrawal the § 103(a) rejection of claim 8.

B. Conclusion

In view of the above amendments and remarks, applicants respectfully request that Examiner pass this application to issuance. If any points remain at issue which can best be resolved by way of a telephonic or personal interview, the Examiner is kindly requested to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

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